NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Dongguan Tian Ren He Yi intelligent Co., LTD
Model Tested: KN95 Mask
Date Tested: August 3, 2020

These findings pertain to the Dongguan Tian Ren He Yi intelligent Co., LTD, Model KN95 Mask. The packaging and labeling for this product indicates that it meets GB2626-2006 (the Chinese standard for Respiratory Protective Equipment – Non-Powered Air-Purifying Particle Respirator).

Ten respirators were submitted for evaluation. The samples were tested using a modified version of NIOSH Standard Test Procedure (STP) TEB-APR-STP-0059. This modified assessment plan can be found here.

No certificate of approval was provided with the samples received; therefore, the authenticity of the claims cannot be validated.

The maximum and minimum filter efficiency was 90.35% and 78.20%, respectively. All respirators measured less than 95%.

While the above-listed product classification has similar performance requirements to NIOSH-approved devices, NIOSH does not have knowledge about the sustained manufacturer quality system and product quality control for these products. NIOSH also does not have knowledge about the product’s handling and exposures after leaving its manufacturer’s control.

In addition, this product is an ear loop design. Currently, there are no NIOSH-approved products with ear loops; NIOSH-approved N95s have head bands. Furthermore, limited assessment of ear loop designs, indicate difficulty achieving a proper fit. While filter efficiency shows how well the filter media performs, users must ensure a proper fit is achieved.

This assessment is not a part of the NIOSH respirator approval process and will in no way lead to or preclude NIOSH approval through the official approval process. This assessment was developed as an assessment of the filter efficiency for those respirators represented as certified by an international certification authority, other than NIOSH, to support the availability of respiratory protection to US healthcare workers due to the respirator shortage associated with COVID-19. Only particulate filter efficiency was assessed.

The results provided in this letter are specific to the subset of samples that were provided to NPPTL for evaluation.

These results will be used to update the CDC guidance for Crisis Capacity Strategies (during known shortages).
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Evaluation of International Respirators

Test: Modified TEB-APR-STP-0059
Date Tested: August 3, 2020
Report Prepared: August 4, 2020
Manufacturer: Dongguan Tian Ren He Yi intelligent Co., LTD
Item Tested: KN95 Mask
Country of Certification: China (GB2626-2006)

<table>
<thead>
<tr>
<th>Filter</th>
<th>Flow Rate (LPM)</th>
<th>Initial Filter Resistance (mmH₂O)</th>
<th>Initial Percent Leakage (%)</th>
<th>Maximum Percent Leakage (%)</th>
<th>Filter Efficiency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>85</td>
<td>10.1</td>
<td>12.6</td>
<td>12.6</td>
<td>87.40</td>
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<tr>
<td>2</td>
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<td>13.3</td>
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</tr>
<tr>
<td>3</td>
<td>85</td>
<td>4.4</td>
<td>19.9</td>
<td>19.9</td>
<td>80.10</td>
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<tr>
<td>4</td>
<td>85</td>
<td>6.6</td>
<td>11.4</td>
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<tr>
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<td>9.7</td>
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<tr>
<td>6</td>
<td>85</td>
<td>6.7</td>
<td>9.65</td>
<td>9.65</td>
<td>90.35</td>
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<td>83.70</td>
</tr>
<tr>
<td>9</td>
<td>85</td>
<td>5.1</td>
<td>21.8</td>
<td>21.8</td>
<td>78.20</td>
</tr>
<tr>
<td>10</td>
<td>85</td>
<td>5.0</td>
<td>21.3</td>
<td>21.3</td>
<td>78.70</td>
</tr>
</tbody>
</table>

Minimum Filter Efficiency: 78.20%  Maximum Filter Efficiency: 90.35%

- The test method utilized in this assessment is not the NIOSH standard test procedure that is used for certification of respirators. Respirators assessed to this modified test plan do not meet the requirements of STP-0059, and therefore cannot be considered equivalent to N95 respirators that were tested to STP-0059.
- Respirators tested may not be representative of all respirators with the same certification mark. NIOSH has no control over suppliers and distributors of respirators certified by other national or international parties.
- This assessment is not a confirmation that it conforms with any or all of its specifications in accordance with its certification mark.
- This assessment was not a part of the NIOSH approval program. These results do not imply nor preclude a future approval through the NIOSH respirator approval program.
We are the waves of the same sea
the peoples of the same earth

[Usage method]
1. Place the nose clip over the mask. Put the mask over your chin.
2. After pulling the ear belt to the ear, adjust position as comfortable as possible.
3. From the middle of the nose clip to both sides press while moving until the nose clip fits the bridge of the nose.
4. Check mask and face cohesion.

[precautions]
1. When the oxygen concentration is lower than 19.5% in anoxic environment, this mask is not suitable for use.
2. The concentration of pollutants is too high to endanger life or health. It is not suitable to use this mask when the degree is high.
3. This mask shall not be used to protect harmful gas or steam.
4. When it is found that the mask is contaminated, damaged or the respiratory resistance changes, the mask should be replaced in case of major conditions.

[storage] store at room temperature and dry place.
[production date]
[validity period]
Under the specified storage conditions, the validity period is three years.

MADE IN CHINA
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CERTIFICATE OF CONFORMITY

The product passes the inspection and is delivered to the factory.

Product Name: KN95 Mask
Quantity: 10pcs
Material: 40% Non-woven 30% Meltblown 30% Hot air cotton
Executive standard: GB2626-2006
Production lot: 2020-04-27
date of manufacture: 2020-04-27
QC Staff: 03
Term of validity: 2 Years
Manufacturer: Dongguan Tian Ren He Yi intelligent Co., Ltd
Address: Room 2 3/F Tower A NO 3 Yin Song Road Qing xi Town Dongguan
Place of Origin: China
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